DEPARTMENT OF HEALTH AND HUMAN SERVICES

93550A

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

October 4, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 03-01

Luis M. Bettencourt, Owner
Bettencourt Dairies
2860 South 2300 East
Wendell, Idaho 83355

WARNING LETTER

Dear Mr. Bettencourt:

An investigation at your dairy located at 2860 South 2300 East, Wendell, Idaho, by our investigator on August 21-22, 2002, confirmed that you offered animals for sale for slaughter as food in violation of Section 402(a)(2)(C)(ii), and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

A food is adulterated under Section 402(a)(2)(c)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act.

- On January 8, 2002, you sold a cow with back tag #82 NE 663 identified on USDA Case #01-0930-ID, Form #422240, for slaughter as human food to [redacted] USDA analysis of tissue samples collected from that animal identified the presence of penicillin in the kidney at 0.82 parts per million (ppm), and in the liver at 0.08 ppm.
- On January 18, 2002, you sold a cow with back tag #82 NE 828 identified on USDA Case #01-0930-ID, Form #422254, for slaughter as human food also to [redacted] USDA analysis of tissue samples collected from that animal identified the presence of sulfadimethoxine in the liver at 5.22 ppm, and in the kidney at 2.78 ppm.

A tolerance of 0.05 ppm has been established for residues of penicillin in edible tissues of cattle (Title 21 Code of Federal Regulations 556.510). A tolerance of 0.1 pm has been established for

residues of sulfadimethoxine in edible tissues of cattle (Title 21 Code of Federal Regulations 556.640). The excess residues of these drugs in edible tissue from these animals causes the food to be adulterated.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs from edible tissues; you have no animal medication records that would identify which animal had been medicated, what date the treatment was administered, what type and dosage of medication had been used, and what the withdrawal times should be; and you lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operations and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to bring your firm into compliance with the law. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Elrand, Compliance Officer at (425) 483-4913.

Sincerely,

Charles M. Breen
District Director

Enclosure:
Form FDA 483

cc: (w/copy of FDA-483):
Lael Alberg, DVM
U.S. Department of Agriculture
Food Safety & Inspection Service
Western Regional Office
620 Central Avenue, Building 2C
Alameda, California 94501